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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/849,525	08/29/1997	GHITA LANZENDORFER	435-WCG	3976

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/849,525

Applicant(s)

LANZENDORFER ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Status of the claims

1. Amendment filed on November 22, 2002 has been entered ("Amendment").
Claims 19-33 are now pending. Any rejection made in previous Office Action that is not addressed in this Office Action is considered obviated.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 32-33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al US Patent 5,145,781.
3. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant argues that Suzuki does not teach alpha-glucosylrutin. In reply, Examiner states that the instant claims are directed to glucosylrutin; Suzuki et al disclose α -glycosyl rutin which is a polymer of monomeric units of one or more α -glucosyl residues such as α -glucosyl rutin and α -maltosyl rutin. Suzuki then discloses purification of such polymers to its elemental monomeric units such as α -glucosyl rutin (see example 2-A; col 11, lines 15-55; col 14, lines 2-41). This purified product then is used in cosmetic creams exemplified in example B-15, col 19, lines 55-67. Such flavonoid is a species of glucosylrutins instantly claimed (see claim 32, line 6).
Accordingly, as stated in the Office Action filed on May 5, 2002, Paper No. 30 ("Office Action"), Suzuki discloses flavonoid compositions that are encompassed by the instant claims. Therefore, Suzuki et al anticipates the limitations of the instant claim.

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4. Claim 25-31 stand rejected under 35 U.S.C. 102(e) as being anticipated by N'Guyen et al US Patent 5,431,912.

5. Applicant argues that Examiner does not point out the specific flavonoids instantly claimed. *See Amendment* at page 5. Frankly, Applicant's arguments are not understood. Examiner has explicitly stated and made of record why N'Guyen patent anticipates the limitations of the instant claims. For example, in the Office Action Examiner stated that N'Guyen discloses cosmetic compositions comprising one or more flavonoids, caffeic acid derivatives and an antioxidizing agent such as beta carotene. *See Office Action* at Page 6. This is clearly within the scope of the pending claims. Examiner then has cited the abstract, col 4, lines 15-21, examples 1-5, col 8, lines 6-12. *Id.* One of ordinary skill in the art viewing said parts of the N'Guyen patent would understand that N'Guyen patent explicitly recited the use of known flavonoids that are encompassed by its formula IV and V such as rutin, quercetin, naringenin, chrysin because such flavonids are clearly enumerated and exemplified. Again, see col 4, lines 15-20, and examples 1-5.

6. Further, Examiner has clearly stated that the caffeic acid derivatives of N'Guyen anticipate the limitations of the instantly claimed cinnamic acid (col 2, lines 65-67; col 3, lines 1-12; col 7, lines 58-66; example 4). *Id.* From this statement, one of ordinary skill in the art viewing N'Guyen's patent would know that Cinnamic Acid, and Caffeic acid are analogous terminologies in the art (see for example, Registry Number 331-39-5, Copyright 2003 ACS). The caffeic acids set forth in col 3, lines 1-12 of N'Guyen fall within the same hydroxycinnamic acid derivatives instantly claimed. Col 3, line 1-9

clearly discloses similar hydroxycinnamic acid derivatives of the instant claims. In fact, such derivatives are exemplified in examples 1-5 including methyl caffeate and methyl 2,5 dihydroxy-4-methylphenyl-acetate.

7. Finally, Examiner clearly stated that N'Guyen explicitly discloses topical application of his compositions for protecting the skin from oxidation (see col 5, lines 39-47). *Id.* Moreover, col 5, lines 59-61 shows the intended topical use of N'Guyen's formulations. Therefore, N'Guyen anticipates the instant claim for the reasons of record.

8. Claims 19-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over N'Guyen et al US patent 5,587,171 in view of Middleton et al (Middleton) (Middleton and Chitha, *The Flavonoids, Advances in Research Since 1986*, 1994, Chapman & Hill, London, Ch. 15, pp 619-645), Harrison's (*Harrison's Principles of Internal Medicine*, 1994, New York, McGraw-Hill, Inc., 13th edition, pp. 309-313).

9. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, all elements of the pending claims are taught by the cited references and therefore, their combined teachings render the instant claims obvious

Specifically, Applicant argues that Examiner has conceded to the fact that N'Guyen does not teach the topical application of flavonoids for treating immunosuppression caused by UVB. See *Amendment* at page 6. This conclusion is simply inaccurate. In the Office Action, Examiner merely stated "N'Guyen does not explicitly recite applications of his compositions on a subject for treating immunosuppression caused by UVB." This is not to say that N'Guyen is void of any teachings for topical application of flavonoids for treating UVB associated conditions, rather it points out on the N'Guyen implicit teachings that his compositions can be applied topically for such immunosuppressive effects encompassed by the instantly recited phrase "immunosuppression caused by UVB."

As Examiner has set forth in previous Office Action, immunosuppression is viewed to encompass any type of biological effects that cause attenuation of immune system. See Office Action, at page 7. N'Guyen compositions is an antioxidizing system comprising one or more flavonoids including rutin, quercetin, and sugar derivatives thereof; caffeic acid derivatives and an antioxidizing agent such as beta carotene. *Id.* Further, Examiner has pointed out tha N'Guyen teaches the use of said compositions as anti-sun creams and for protecting the lipids of the skin from oxidation. *Id.* From these teachings, one of ordinary skill in the art would deduce that topical or cosmetic application of N'Guyen's compositions would provide antioxidizing effects including protecting the lipids of the skin. Thus, protecting lipid of the skin from oxidation and subsequent damage would attenuate immunosuppression to the extent that falls within the scope of the instant pending claims. Such teachings is implicit to protective function

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of N'Guyen's composition against UV light. Thus, the N'Guyen's teachings only lack an explicit statement about beneficial effects of flavonoids on the immune system.

This deficiency is clearly provided by Middleton and Harisson. Middleton is merely used to show the general knowledge available in the art for the beneficial effects of topical flavonoids in improving immunosuppressive conditions regardless of their etiology (Office Action, at 7). Applicant contends that the topical use of Middleton is for other uses than immunosuppression. However, no evidence has been provided to indicate that topical application in fact provides unexpected results when compared to other routes of administration. Further, N'Guyen clearly teaches topical administration of flavonoids, therefore, expectation of beneficial effects is clearly within the teachings of N'Guyen.

Moreover, Harisson shows the general knowledge in the art about the etiology of solar radiation and systemic immune response caused by UV-B exposure (see pp 309 last paragraph). Accordingly, the immunosuppression caused by UV-B is caused by the induction of suppressor T cells throughout the body. Thus, Middleton and Harisson's collectively bridge the implicit teachings of N'Guyen to other beneficial utilities including immunosuppression of skin caused by UVB, because as taught in Harisson's, UVB immunosuppression is dependent on the activity of T-lymphocyte applying which as taught by Middleton, can be controlled by topical administration of a flavonoid of choice including those taught by N'Guyen. Thus, it would have been obvious to use N'Guyen's formulations topically to modulate immune suppressions caused by UV-B exposure.

Double Patenting

10. Claims 19-33 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 5,952,373 ('373) and claims 1-5 of U.S. Patent 6,121,243 ('243) for the reasons of record.

11. Claim 19-33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 009/656598 and 09/540007 for the reasons of record.

New Grounds of Rejection

12. Claims 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Raff US Patent 4,525,343 or JP 77044375 ("JP '375").

Raff discloses topical compositions comprising hesperidin and an antioxidant such as benzoate or ascorbate salts. Applicant is informed that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, since Raff's compositions contains all elements of the instant claims, they anticipate the instant claims (see example 1-6).

JP '375 discloses cosmetic compositions comprising hesperidin and an antioxidant such as rutin (see abstract). Thus, it anticipates the limitations of the instant claims.

Conclusion

a. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
February 15, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200